

REMARKS

Claims 29-43 are pending, wherein claims 29, 32, 33, 35, 38 and 39 have been amended and new claims 42 and 43 were added. Reconsideration and allowance for the above-identified application are now respectfully requested.

As discussed in the Application, the present invention is directed to suture separation and organization devices for use with graft tensioning devices. The graft tensioning devices are used to independently apply appropriate tensile stresses to sutures attached to multiple strands of a soft tissue implant during joint repair surgery. Exemplary suture separation and organization devices are illustrated in Figures 7-10 of the Application. Figures 1-6 illustrate exemplary graft tensioning devices that can be used in conjunction with the suture separation and organization devices. As shown in Figures 7 and 8, the suture separation and organization devices according to the invention are able to organize and separate tensioned sutures in a desired manner so as to maintain desired spacing between the various tensioned sutures. Figure 9 shows tensioned sutures that are organized using an alternative embodiment of a suture separation and organization device.

The inventive suture separation and organization devices are designed so as to be releasably attachable to a graft tensioning device. In other words, the suture separation and organization devices do not form an integral part of the graft tensioning device. Instead, the two are slidably attached together prior to and after providing appropriate tension to a graft tissue device and organizing the sutures in a desired manner. Organizing the sutures facilitates the insertion of an interference screw into the bone tunnel by keeping the sutures out of the way. This is best illustrated in Figure 8 although it is readily apparent that the suture separation and organization device shown in Figure 9 also provides the same functionality as the device in Figure 8.

The Office Action rejects claims 29-40 under 35 U.S.C. § 103(a) as being unpatentable over Lewis (US 4,950,271) in view of Fallin (US 2004/0254593).¹ The claims as amended distinguish over the applied art, which fails to disclose or suggest the combination of elements recited in the claims as now amended.

Claim 29 as amended discloses a combination of elements that is neither taught nor suggested by the combination of Lewis and Fallin. For example, Lewis fails to disclose or

¹ Because Fallin is only citable under 35 U.S.C. § 102(e), Applicants do not admit that Fallin is in fact prior art but reserve the right to remove Fallin as a reference by establishing an invention date that predates the filing date of Fallin.

suggest a plurality of attachment passages or recesses in the body for releasably attaching the body to a graft tensioning device during use, each passage or recess being sized and positioned so as to slidably receive therein a corresponding post of a graft tensioning device. Instead, Lewis discloses a device that lacks any structure corresponding to the passages or recesses element of claim 29. Instead, as shown in Figure 3, the alleged "body" 42 of Lewis includes a threaded hole into which a threaded screw is threadably attached, not slidably received.

Lewis also fails to disclose respective hollow post guides projecting from a second surface of the body so as to maintain space between the patient's leg and the second surface of the body when the suture separation and organization device is in use. Instead, as best shown in Figure 3 and also illustrated in Figure 4, the alleged "body" 42 lies essentially flush with the patient's leg. In Figure 3, only the patient's bone is shown, not the flesh surrounding the bone. Therefore, any space between plate or body 42 in the bone 35 is merely there because there is obviously flesh in between the two. Hence, Lewis fails to disclose any structure corresponding to the hollow post guide element recited in claim 29.

Lewis is further deficient in that Lewis fails to disclose a first plurality of suture retention recesses or protrusions disposed in an upper perimeter of the body and a second plurality of retention recesses or protrusions disposed on the lower perimeter of the body. For this reason, the Office Action relies on Figure 9 of Fallin as allegedly disclosing this missing element. However, Fallin is not properly combinable with Lewis because it does not in any way relate to the organization of sutures during joint repair surgery, nor does it provide structures that are designed to be capable of organizing sutures. Fallin is therefore nonanalogous to both the claimed invention and also Lewis and is therefore not properly combinable with Lewis in order to obtain the invention of claim 29.

Moreover, even if one were to combine Fallin and Lewis, the combined teachings of these two references does not disclose or suggest the combination of elements recited in claim 29. In order for the device shown in Figure 9 of Fallin to be used with the Lewis device, it must by necessity be capable of being releasably attached to the graft tensioning device of Lewis without a complete redesign of the attachment mechanism of Lewis and/or the device shown in Figure 9 of Fallin. In fact, a cursory inspection of the two references indicates that it would be impossible attach the two devices together. Moreover, there does not appear to be any reasonable way in which the two devices could be readily modified so as to work together and provide the functionality of the suture separation and organization device of claim 29.

Moreover, it is clear that recess 138 of the Fallin device does not pass through the center of the body and so therefore fails to satisfy the passageway or recess element of claim 29. Whereas Lewis appears to disclose a central recess, once the alleged body 42 according to Lewis is modified so as to have the recess structures shown in Figure 9, the alleged passageway or recess would then be provided by recess 138 of Fallin, which fails to provide the structure recited in claim 29.

In view of the foregoing, Applicants submit that claim 29 as amended is patentable over Lewis and Fallin.

Claims 30-34 and 42 depend from claim 29 and are likewise patentable over the combination of Lewis and Fallin. Moreover, they recite additional elements that may further distinguish over the applied art. For example, claim 42 requires the passageway or recess passing through the center of the body to be substantially cylindrical (*see* Figures 7, 9, 9A, 9B and 10 of the present application).

Claim 31 further recites that each respective hollow post guide projects orthogonally from the second surface of the body. In contrast, there are no hollow post guides within either Lewis or Fallin such that it would be impossible for such nonexistent structures to project orthogonally from any other structure.

Claim 32 further specifies that the pair of upper suture retention recesses or protrusions are spaced apart and positioned so as to provide a first spacing distance between a pair of corresponding upper sutures, and the pair of lower suture retention recesses or protrusions are spaced apart and positioned so as to provide a second spacing distance between a pair of corresponding lower sutures that is substantially equal to the first spacing distance. This concept is illustrated in Figures 7, 8 and 9 of the present application. The Office Action acknowledges that Lewis does not disclose any suture retention recesses or protrusions but relies on Figure 9 of Fallin for this missing structure. However, it is clear that recesses 120 and 120' on one side of the Fallin device do not provide the same spacing distance as the recesses 140 and 140' on the other side of the device of Figure 9. Moreover, since Fallin has nothing to do with organizing tensioned sutures during joint repair surgery, there was no teaching, suggestion, motivation or other reason why one of skill in the art would have modified the Fallin device to have the spacing specified in claim 32 as amended.

Claim 33 claims a tensioning system that utilizes the suture separation and organization device of claim 29 and a graft tensioning device, wherein the graft tensioning device includes a

plurality of posts designed so as to be slidably receivable through the attachment passages or recesses in the body of the suture separation and organization device. It is clear that the Lewis device does not include any posts designed to be slidably receivable through attachment passages or recesses in a body of a suture separation and organization device. Instead, threaded bolts are used to attach the device 50 on to the body 42, as clearly shown in Figures 2-4 of Lewis.

Independent claim 35 alternatively claims a tensioning system for applying variable tension to a plurality of suture strands and also organizing the suture strands preparatory to fastening a soft tissue graft within the bone tunnel. To this end, the tensioning system of claim 35 includes a graft tensioning device and a suture separation and organization device. The graft tensioning device includes means for removably attaching the graft tensioning device to a suture separation and organization device. The suture separation device includes upper and lower suture retention recesses that provide first and second spacing distances between pairs of corresponding upper and lower sutures that are substantially equal to each other. An example of this is shown in Figure 7-9 of the application. In contrast, and as discussed above in relation to claim 32, the Lewis device does not include any such recesses or protrusions. Moreover, Fallin fails to disclose or suggest recesses or protrusions that provide first and second spacing distances that are substantially equal to each other. This is readily apparent in Figure 9 of Fallin. In view of the foregoing, Applicants submit that claim 35 as amended is unobvious over the combination of Lewis and Fallin.

Claims 36-41 depend from claim 35 and are likewise patentable over the combination of Lewis and Fallin. In addition, they recite additional elements that may further distinguish over these references. For example, claim 38 specifies that the passageway or recess passing through a center of the body is substantially cylindrical. In sharp contrast, the passageway 138 of Fallin is clearly not cylindrical, and there was no teaching, suggestion, motivation or any other reason why one of skill in the art would have selectively included the passageways 120, 120', 140 and 140' of Fallin while not including the passageway 138. To do so would require the use of impermissible hindsight, using claim 38 as a guide to reconstruct the invention from unrelated teachings of the applied art.

Claim 39 further specifies that the attachment means for removably attaching the body means to the graft tensioning device comprises a plurality of attachment passages or recesses in the body which are sized and positioned to slidably receive therein a corresponding post of the graft tensioning device, and wherein the post comprises means for removably attaching the graft

tensioning device to the suture separation and organization device. In contrast, as clearly shown in Figures 2-4 of Lewis, tensioning device 50 is attached to body 42 by means of threaded bolts. As such, there can be no slidable attachment between the graft tensioning device and the suture separation and organization device as required in claim 39.

Claim 40 further recites that the attachment passages or recesses are defined by respective hollow post guides projecting from the second surface of the body so as to maintain space between a patient's leg and the second surface of the body when in use. In contrast, body 42 of Lewis is designed so as to lie flush with a person's leg (*see* Figures 2 and 4 of Lewis).

Claim 43 represents claim 41 as previously presented rewritten in independent form. The Office Action indicates that claim 41 as previously presented would be allowable if rewritten in independent form so as to include the limitations of the base claim and any intervening claims. Accordingly, new claim 43 defines subject matter that was previously deemed to be allowable over the art of record.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 2nd day of March 2009.

Respectfully submitted,



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